



1564 '03 APR -3 A8:38

March 31, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD USA 20852

Re: Comments on rules proposed by the Department of Health and Human Services'
Food and Drug Administration (FDA) under the [US] Public Health Security and
Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act).
Docket No. 02N-0278

To Whom It May Concern:

The Province of New Brunswick, Canada, shares the concerns of the United States on the need to examine all potential routes for terrorism after the tragic events of September 11, 2001. A safe, secure and consistent food supply is a critical element of public well-being, one which could be overlooked in the simple pursuit of profits. Our food exporters also appreciate that you will endeavor to use the pre-notification period to share information with them on bioterrorism concerns that your sources have identified prior to shipment. This can only serve to help consumers in both of our countries who could be at risk.

At the same time, however, a reasonably flexible regulatory system is a critical element to ensure a consistent supply of safe food at affordable prices. Thus, we would suggest that prior notice provisions should utilize risk assessments to stratify the type of notice period required by such factors as geographic origin, final destination and product type. In particular, New Brunswick would recommend that most of its products be granted a 4-hour pre-notification period with amendments/updates, based on the factors discussed below.

Many New Brunswick animal feed products are shipped to rather "local" markets in Maine as backhaul. This backhaul requirement creates a great deal of uncertainty as to the truck's arrival time for loading and makes accurate notification a day in advance almost impossible. This could have the unintended consequence of overloading the pre-notification system as companies notify (and later cancel) the same shipment for several days running, until such time as the trucks are actually loaded.

The main exports from New Brunswick affected in this manner would be hay/forage and salmon feed. Maritime companies produce the only specialized salmon feed available to Maine's aquaculture operations, and since this feed is an expensive component, these operations do not carry a large inventory. Delays at the border due to any errors or down-

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time in the pre-notification system could put Maine salmon farms at considerable risk of fish losses. Given the low (direct) human risk of animal and fish food and Maine's reliance on New Brunswick products, we recommend that a minimum 4-hour pre-notification period (with updates) be instituted for these products.

Similarly, the New England seafood market relies almost exclusively on the Maritimes for its scallops and sea urchin roe. Both are extremely perishable and both can only be harvested (and thus shipped) when the weather cooperates, something notoriously difficult to predict in this region. Without additional flexibility in the pre-notification process, these shippers will be forced to submit several notifications (and subsequent cancellations) to enable timely export once the product is actually in hand. Thus, a 4-hour pre-notification (with updates) should also be instituted for these products.

Salmon and lobster are our largest export to the New England region, and while it is easier to plan the harvest and shipment of these species, there are still difficulties. The customs data on same-day shipments utilized in the preparation of these proposed regulations was sadly lacking – one company alone estimated that at least 5 out of 30 shipments per day are placed the same day. Because these are very fresh products, customers prefer to wait until the end of the day to place their order. These orders are then loaded onto trucks between 5:00p.m. and midnight before heading to the border. For Atlantic salmon (sold as fillets, skewers, roasts, steaks, etc.), the exact product code might not be predictable if the fish size does not lend itself to the pre-ordered cut. Given the assessment of bioterrorism risk would be similar for each of these product types, the decision on how to allocate inspection resources would not be affected by changes within these classifications. Thus, we would recommend that the 4-hour minimum (with updates) be instituted for these products and/or the product codes should be more general (eg. fresh Atlantic salmon, any cut) until such time as an amendment can be provided (2 hours prior to arrival at the border).

Other products for which pre-notification will be difficult include wild blueberries and cranberries. These are harvested intensely over a 6-week period in late summer and fall and require immediate bulk transportation to processing plants, located in Maine. These processors are dependent on New Brunswick berries to maximize their capacity utilization (and thus cost efficiency). While it may be possible to estimate the number of loads setting out the following day, precision can only be obtained late in the same day they are shipped. In this case, given the farms' proximity to the Calais/St. Stephen border crossing and the ambient temperatures at that time of year, a maximum 4-hour pre-notification would be necessary to prevent spoilage.

Potato exports, be they seed, table stock or processed, are also exported into the United States from New Brunswick. More than 80% of table stock shipments are same-day orders since buyers operate off of computer-based systems that do not allow for any inventory build-up. In addition, there is often a last-minute effort required to obtain the necessary trucks. Pre-notification that includes carrier identification at least 12 hours in advance of arrival would be completely impossible without a major restructuring at the buyer and trucker level. This seems unlikely and so a 12-hour period will cause a major

trade impediment if left unchanged. In this case, a 4-hour pre-notification for these products would be required with the option of providing carrier identification as an update or amendment 1 or 2 hours in advance of arrival.

Many Canadian processors have recently undergone thorough inspections to obtain certification from the FDA. New Brunswick would suggest that, once the pre-notification rules have been established, at the operations level of the FDA the frequency of inspections should reflect the FDA certification status of the processing plant. In addition, many companies are investing heavily to increase security in order to participate in the C-TPAT program through our respective customs services – this should also be a factor in determining the requisite level of inspections. Adding fields in the pre-notification electronic form to identify the shipment as coming from such a plant should be the minimum acknowledgement of these related initiatives.

Approximately \$3 million of agri-food and seafood products are shipped across our two busiest border crossings each day. Should the New Brunswick products mentioned above be assessed as low-risk, as we anticipate, it is likely that FDA inspectors will be in greater demand at other ports of entry. Provided a pattern of shipments is established, then, we believe a 4-hour advance notice should suffice for these products from this province.

In addition, it is of critical importance that the pre-notification requirements of the FDA be coordinated with those of the US Customs Service. Realizing your computer systems will not be conversant with each other initially, every effort must be made to avoid duplication and/or conflicts (ie. product codes should be consistent). Further, in the event of a breakdown in your pre-notification system the onus should be on the FDA to provide flexibility. For instance, where products are pre-assessed as low-risk and the system for pre-notification has crashed, pre-notification for these products should be waived so that the requisite information can be provided at the time of arrival at the customary border crossing.

With respect to the requirement for a US-resident agent, most New Brunswick exporters would be able to comply with this clause for facility registration (Docket No. 02N-0276), if necessary. However, for pre-notification purposes, requiring a US-resident agent to submit would cause serious problems for nearly all of New Brunswick's exporters. Not the least of which concerns the transfer of legal ownership of the goods, which occurs only upon arrival at the customer. The ownership status of the goods in-transit (and potentially in holding at the border crossing) could reduce the impetus for non-owners to comply properly with the pre-notification requirements.

If the ultimate desire of the legislation is to obtain the most accurate information as soon as possible, then this would be best served by allowing the exporters themselves to submit the pre-notification (and amendments/updates). Most customers would only be able to submit the notice (and any updates) during their hours of business, which are usually considerably shorter than for the shipping department at the exporter. Requiring the customer to submit the notification would delay the process and introduce another potential source for error, particularly where they are not aware of any minor product

substitutions (i.e. salmon steaks instead of salmon fillets) or necessary last-minute changes in carrier identification.

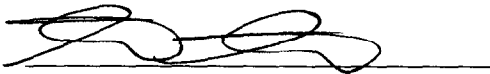
Issues surrounding loads destined for several customers also create unparalleled complications for many smaller processors who service the Maine market almost as an extension of their New Brunswick market. Relying on small grocery stores, often lacking an internet access, to pre-notify each purchase of donuts, for instance, delivered in a single load creates the potential for several errors with each shipment.

New Brunswick, then, recommends that our exporters be permitted to submit the pre-notifications and any amendments/updates as necessary. If this isn't possible for all, then some recognition or registration of bonded companies (resident in Canada) who could serve this function should be developed. At the very least, all FDA-registered facilities or participants in the U.S. Customs - Trade Partnership Against Terrorism (C-TPAT) should be permitted to submit their own pre-notifications, amendments and updates either as exporter or as "importer of record".

In closing, a major benefit of food products from New Brunswick to the United States marketplace is New Brunswick's proximity and the subsequent freshness and safety of its products. For several of these foodstuffs, however, pre-notification the day prior to arrival at the border crossing would prove to be a serious barrier to trade and, in some instances, would endanger the operations of several customers located in the United States. In addition, requiring that a third-party submit such notices would introduce too many errors in the pre-notification process.

To summarize, New Brunswick requests that its food exporters be permitted to provide a 4-hour pre-notification. We would also request that updates and/or amendment also be allowed on the carrier identification, the cut/package size (but not species) and the exact quantities. Finally, we request that our exporters be allowed to submit this pre-notification and amendments/updates on their own behalf. It is hoped that this rather detailed discussion will provide the information necessary for the FDA to justify the requested modifications to its pre-notification rules.

Yours sincerely,



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